Notice of Allowability	Application No.	Applicant(s)	
	09/560,597	MCALINDON ET AL.	
	Examiner	Art Unit	
	Rachel L. Porter	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the Amendment filed12/22/06*. R.P.

2. ☒ The allowed claim(s) is/are *1-14,16-18 and 20-38*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☒ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☒ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date 20070329.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Charles Gagnebin (Reg. No. 25,467) on March 26, 2007.

The application has been amended as follows:

Please cancel claim 28.

Claims 1, 8, and 29-38 should now appear as follows:

Claim 1. (Currently Amended) A method of conducting a clinical trial of a test substance over the internet from a primary site, comprising the following steps:

- assigning, at the primary site, a unique identifier and a unique log-in password to at least one clinical trial participant located at a remote internet site distinct from the primary site, the unique identifier and the unique log-in password for accessing protected information from the primary site;
- providing to the participant, responsive to receipt by the primary site of the unique identifier and the unique login password, instructions on: using the test substance; accessing and completing at least one evaluation form from a website

maintained at the primary site; and returning electronically said at least one evaluation form to the primary site;

- providing, responsive to receipt by the primary site of the unique identifier and the unique log-in password, said at least one evaluation form in electronic format for use by the participant, said at least one evaluation form having a question and answer section, presenting at least one question, that when completed by a participant using the test substance, provides information regarding one or more effects of the test substance on the participant completing the evaluation form;
- modifying, while the participant completes said at least one evaluation form in electronic format, said presentation of at least one question presented in said at least one evaluation form based at least in part upon one or more responses provided by the participant on at least one said evaluation form currently being completed by the participant and an evaluation form previously completed by the participant;
- completing, by the participant, said at least one evaluation form; and
- compiling in an investigator accessible form data regarding at least one of said one or more effects of the test substance on the participant from information from at least one received and completed evaluation form returned by the participant to at least one investigator conducting the clinical trial.

Claim 8. (Currently Amended) A method of conducting a clinical trial of a test substance over the internet, comprising the following steps:

- maintaining, at a primary site, a website that is accessible from remote sites via the internet and that provides information about the clinical trial and minimum eligibility criteria for participants in the clinical trial;
- causing a screening questionnaire to appear over the internet at a remote site, after receipt, at the primary site from the remote site, of a request to display the questionnaire, wherein the questionnaire has portions for receiving information that enables a determination of whether a candidate, upon whose behalf the questionnaire is completed, is eligible to be a participant in the clinical trial;
- obtaining the candidate's informed consent to participate in the clinical trial;
- receiving the candidate's completed questionnaire at the primary site via the internet;
- reviewing the received questionnaire and making a determination of whether the candidate is eligible to be a participant in the clinical trial according to a set of predetermined criteria;
- after receipt of the candidate's informed consent by at least one investigator, causing information transfer between the primary site and the remote site for the purpose of confirming the existence, identity, and eligibility of the candidate to participate;
- assigning, at the primary site, a unique identifier and a unique log-in password to at least one clinical trial participant, the unique identifier and the unique log-in password for accessing protected information from the primary site;

- providing, responsive to receipt by the primary site of the unique identifier and the unique log-in password, to the participant, instructions on: using the test substance; accessing and completing at least one evaluation form from a website maintained at the primary site; and returning electronically said at least one evaluation form to the primary site;
- providing, responsive to receipt by the primary site of the unique identifier and the unique log-in password, said at least one evaluation form in electronic format for use by the participant, said at least one evaluation form having a question and answer section, presenting at least one question, that when completed by a participant using the test substance, provides information regarding one or more effects of the test substance on the participant completing the evaluation form;
- modifying, while the participant completes said at least one evaluation form in electronic format, said presentation of at least one question presented in said at least one evaluation form based at least in part upon one or more responses provided by the participant on at least one said evaluation form currently being completed by the participant and an evaluation form previously completed by the participant;
- completing, by the participant, said at least one evaluation form; and
- compiling in an investigator accessible form data regarding at least one of said one or more effects of the test substance on the participant from information from at least one received and completed evaluation form returned by the participant to at least one investigator conducting the clinical trial.

Claim 29. (Currently Amended) A computer executable program code embodied on a computer readable medium, for conducting, with a processor and memory for said code, a clinical trial of a test substance over the internet from a primary site, comprising:

- program code for assigning, at the primary site, a unique identifier and a unique log-in password to at least one clinical trial participant located at a remote internet site distinct from the primary site, the unique identifier and the unique log-in password for accessing protected information from the primary site;
- program code for providing, via the internet, responsive to receipt by the primary site of the unique identifier and the unique log-in password, to at least one clinical trial participant located at a remote site distinct from the primary site, instructions on: using the test substance; accessing and completing at least one evaluation form from a website maintained at the. primary site; and returning electronically said at least one evaluation form to the primary site;
- program code for providing, responsive to receipt by the primary site of the unique identifier and the unique log-in password, said at least one evaluation form in electronic format for use by the participant at the remote site, said at least one evaluation form having a question and answer section including at least one question that, when completed by a participant using the test substance, provides information regarding one or more effects of the test substance on the participant completing the evaluation form; and
- program code for modifying, while the participant completes said at least one evaluation form in electronic format, at least a portion of the question and answer

section included in said at least one evaluation form based at least in part upon one or more responses provided by the participant on at least one of said evaluation form currently being completed by the participant and an evaluation form previously completed by the participant; and

- program code for compiling into a central database at the primary site, investigator accessible data regarding at least one of said one or more effects of the test substance on the participant from information from at least one received and completed evaluation form returned by the participant to at least one investigator conducting the clinical trial.

30. (Currently Amended) The computer executable program code embodied on a computer readable medium of claim 29, further comprising program code for causing a consent form to appear at the remote site, said consent form having information about the clinical trial, a portion allowing consent to be given to participate in the clinical trial, and a portion allowing consent to be given to release of the participant's medical information to at least one investigator conducting the clinical trial.

31. (currently amended) The computer executable program code embodied on a computer readable medium of claim 30, further comprising program code for receiving and electronically authenticating a consent form completed and returned via the internet by the clinical trial participant.

32. (currently amended) The computer executable program code embodied on a

computer readable medium of claim 29, further comprising program code for screening potential candidates over the internet for eligibility to participate in the clinical trial, including:

- program code for maintaining, at the primary site, a website that is accessible from remote sites via the internet and that provides information about the clinical trial and minimum eligibility criteria for participants in the clinical trial;
- program code for causing a screening questionnaire to appear over the internet at a remote site, after receipt, at the primary site, of a request from the remote site to display the screening questionnaire, wherein the questionnaire has portions for receiving a candidate's information that enables a determination of whether a candidate is eligible to be a participant in the clinical trial; and means for receiving the completed questionnaire at the primary site via the internet.

33. (currently amended) The computer executable program code embodied on a computer readable medium of claim 32, further comprising program code for reviewing the received questionnaire and making a determination of whether the candidate is eligible to be a participant in the clinical trial according to a set of predetermined criteria.

34. (currently amended) The computer executable program code embodied on a computer readable medium of claim 33, wherein the reviewing and determining program code provides for comparing the participant's answers to the questionnaire with a

reference standard comprising conventionally accepted indications of a medical condition for which the test substance's effectiveness in treating is being tested.

35. (currently amended) The computer executable program code embodied on a computer readable medium of claim 33, further comprising program code for informing the candidate, via the internet, of the candidate's eligibility to participate in the clinical trial.

36. (currently amended) The computer executable program code embodied on a computer readable medium of claim 32, further comprising program code for causing information transfer between the primary site and the remote site for the purpose of confirming the existence, identity, and eligibility of the candidate to participate.

37. (currently amended) The computer executable program code embodied on a computer readable medium of claim 29, 31, 32, 35, or 36, further comprising program code for encrypting information transferred between the primary site and the remote site.

38. (currently amended) The computer executable program code embodied on a computer readable medium of claim 29, 30, 31, 32, 33, 34, 35, or 36, further comprising program code for collecting and storing at a secure site accessible by the at least one investigator and by the participant, information from at least one member of the group

consisting of: at least one evaluation form completed and returned by the participant to the at least one investigator; and a screening questionnaire completed and returned by the participant to the at least one investigator.

Allowable Subject Matter

2. Claims 1-7 , 8-14, 16-18, 20-27 and 29-38 are allowed.

3. The following is an examiner's statement of reasons for allowance:

As per method claims 1-7 and 8-14, 16-18, and 20-27 the closest prior art, Colon and Hopp discloses providing screening questionnaires to determine if an individual qualifies for a clinical trial. However, the prior art does not disclose or fairly suggest a combination including the dynamic presentation of questions in screening participants and retrieving data from clinical trials participants online. The prior art does not teach: "modifying, while the participant completes said at least one evaluation form in electronic format, said presentation of at least one question presented in said at least one evaluation form based at least in part upon one or more responses provided by the participant on at least one said evaluation form currently being completed by the participant and an evaluation form previously completed by the participant."

Similarly, as for claims 29-38 the closest prior art, Colon and Hopp does not teach or fairly suggest a combination including a computer generated method or computer program code for modifying, while the participant completes said at least one

evaluation form in electronic format, said presentation of at least one question presented in said at least one evaluation form based at least in part upon one or more responses provided by the participant on at least one said evaluation form currently being completed by the participant and an evaluation form previously completed by the participant."

Based on applicant's specification, the Examiner understands the step of "compiling data in an investigator accessible form data..." to include receiving and electronically and/or physically storing submitted information from the evaluations forms of the candidates/participants. (See pages 10, lines 26-page 11, line 29). Therefore, the examiner understands the claim to recite statutory subject matter.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Drawings

4. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the drawings submitted 4/28/2000 contain certain informalities:

- Figure 1: The boxes labeled 14 and 12a include text that is not legible because of shading.
- The shading in Figures 8A-C and 9 renders some of the text illegible and the margins are improper.

Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Soll et al (US 2003/0055679A1) discloses branching questions for patient diagnosis and treatment.
- Huyn et al (US 2002/00354 A1) discloses a clinical questionnaire with dynamically presented questions.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel L. Porter whose telephone number is (571) 272-6775. The examiner can normally be reached on M-F, 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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